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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/596,101 06/16/00 DE BAETSELIER

P 4432US

EXAMINER

HM22/0808

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P O BOX 2550
SALT LAKE CITY UT 84110

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

08/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

File copy

Office Action Summary	Application N 09/596,101	Applicant(s) DE BAETSELIER ET AL.	
	Examiner Vanessa L. Ford	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 16 June 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- | | |
|-----------|---|
| Group I | Claims 1-3, 11, 13 and 16-17 are drawn to a peptide, classified in class 530, subclass 300. |
| Group II | Claim 4 is drawn to an antibody, classified in class 424, subclass 130. |
| Group III | Claims 5-9 are drawn to a DNA sequence, classified in class 536, subclass 23.1. |
| Group IV | Claims 10 and 14-15 are drawn to a method of making a polypeptide or fragment, classified in class 435, subclass 69.1. |
| Group V | Claims 12 and 18-19 are drawn to a method of treating a disease comprising administering a polypeptide, classified in class 514, subclass 12. |

2. The inventions are distinct, each from the other because of the following reasons:

Groups I, II and III are drawn to different products. Group I is drawn to a peptide.

Group II is drawn to an antibody. Group III is drawn to a DNA sequence. The inventions can be shown to be distinct because they are made by different methods and because they are physically and functionally distinct entities. The polypeptide is made of amino acids whereas the DNA sequence consists of nucleic acids. Amino acids constitute a class of difunctional compounds and are the building blocks from which proteins are constructed and the DNA sequence is not required to produce the protein because the protein can be made synthetically or isolated from nature. The antibodies of Group II are distinct from Groups I and III because antibodies have an inherent

affinity, avidity, and specificity that a nucleic acid or a protein are not capable of expressing and function to mediate an immune response which neither the protein or nucleic acid are capable of. The nucleic acid is not required to make the antibody.

3. Groups I and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the peptide of Group I can be made synthetically.

4. Groups I and V are product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a material different process of using that product (MPEP 806.05(h)). In the instant case the inventions of Group I may be used for a number of different processes that are very much unrelated. For example, the peptide of Group I can be used as an immunogen to stimulate the production of antibodies for use in immunotherapy, as diagnostic reagents in an assay to detect infection and for use as reagents in other processes such as affinity chromatography for purification of antibodies.

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5. Group II and IV are unrelated as a product and a method. Group II and IV are distinct one from the other because the product of Group II is not required in the method of Group IV. Therefore, they are materially distinct and independent from each other as claimed.

6. Group II and V are unrelated as a product and a method. Group II and V are distinct one from the other because the product of Group II is not required in the method of Group V. Therefore, they are materially distinct and independent from each other as claimed.

7. Group III and IV are unrelated as a product and a method. Group III and IV are distinct one from the other because the product of Group III is not required in the method of Group IV. Therefore, they are materially distinct and independent from each other as claimed.

8. Group III and V are unrelated as a product and a method. Group III and V are distinct one from the other because the product of Group III is not required in the method of Group V. Therefore, they are materially distinct and independent from each other as claimed.

9. Group IV and V are drawn to distinctly different methods which differ in the method objectives, method steps and in reagent used. The Group IV is drawn to a

method of making a polypeptide. Group V is drawn to a method of treatment comprising administering a polypeptide.

10. Restriction to one of the following inventions is required under 35 U.S.C. 121:

The inventions are distinct, each from the other because of the following reasons:

Because these inventions are distinct for the reasons given and have acquired a separate status in the art because of their recognized divergent subject matter as shown by their different classification, restriction for examination purposes as indicated is proper. Moreover, in the absence of restriction it would place an undue search and examination burden on the examiner.

11. Applicant is advised that the reply to this requirement to be complete must include an election of invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

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13. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 305-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.



Vanessa L. Ford
Biotechnology Patent Examiner
August 1, 2001



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